PSJ17 Exh 65

From: Matthew Day </O=TEVA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MDAY>
To: Jeffrey Dierks
Sent: 9/2/2014 3:34:16 PM
Subject: FW: TEVA Program this weekend
Attachments: PAIN-40090_Unbranded PAINWeek Presentation_To Faculty_09.02.14.pdf

FYI…

Matt Day
Associate Brand Director – CNS Marketing
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From: Abbas Ebrahim, MD [mailto:AEbrahim@hlxusa.com]
Sent: Tuesday, September 02, 2014 10:59 AM
To: Jeff Gudin MD; mjbmd58@aol.com; pargoff@optionline.net; cargoff@nycap.rr.com
Cc: Matthew Day; Neil Gardiner; Alison Labombarda
Subject: TEVA Program this weekend

All,
Hope you all had a good holiday weekend, and are gearing up for PAINWeek 2014. In preparation for our program on Saturday, September 5, please find attached the slides that we began deliberating in Jersey City a few weeks ago. Please let me know if you have any questions about the content or program, and we look forward to seeing you all later this week!

Best,

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EVOLVING ROLES, SAME GOALS:

THE CHANGING LANDSCAPE OF PAIN MANAGEMENT

PAIN-40090 August 2014

Disclosures

This promotional program was developed by Teva and the faculty are presenting on behalf of Teva

The faculty have received compensation from Teva to make this presentation

Faculty Introductions

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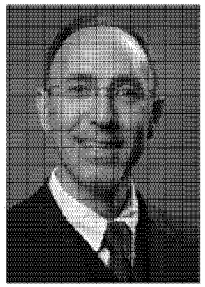

Jeff Gudin, MD
Director, Pain Management and Palliative Care
Englewood Hospital and Medical Center
Englewood, NJ
Clinical Instructor, Anesthesiology
The Icahn School of Medicine at Mt Sinai
New York, NY

Program Overview

- Today's Objectives:
  - Outline some of the options for pain management, focusing on the role of opioids
    - Although efficacious, opioids are subject to misuse, abuse, and diversion
  - Consider the role of HCPs, patients, and government as part of a multifaceted approach to address these issues
  - Discuss how industry may play a role in augmenting a multi-faceted approach through the development of abuse-deterrent opioid formulations
    - Review FDA draft guidance on their development

Test ARS Question

- What percent of your patients are being seen primarily for the treatment/management of pain?
  1. Less than 25%
  2. 25% to <50%
  3. 50% to 75%
  4. Over 75%

Complexities in Pain Management

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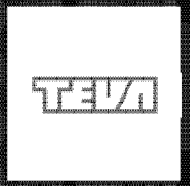


Introduction

- Chronic pain constitutes an immense medical need in the United States
  - Affects over 100 million Americans[1]
  - Results in up to $635 billion annually in direct medical costs and lost productivity[1]
  - Chronic pain may impact routine activities[2]
- Opioids represent an important part of the chronic pain armamentarium[3]
- A large and devastating problem of opioid abuse, diversion, and misuse exists and must be addressed[4]
- A multifaceted approach is needed to ensure that pain management is effectively provided to patients who need it while addressing these concerns
  - Strategies to deal with opioid abuse include educational and regulatory initiatives as well as the development of abuse-deterrent formulations
- The benefits of effective treatment must be weighed against the consequences of inadequate analgesia[5]

1. Institute of Medicine. Relieving pain in America: a blueprint for transforming prevention, care, education, and research. Washington, DC: The National Academies Press; 2011. **2.** McCarberg BH, et al. *Am J Ther*. 2008;15(4):312-320. **3.** Chou R, et al. *J Pain*. 2009;10(2):113-130.e22. **4.** Substance Abuse and Mental Health Services Administration. http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.pdf. Updated October 2, 2013. Accessed March 31, 2014. **5.** American Pain Society. Pain: Current Understanding of Assessment, Management, and Treatments. http://www.americanpainsociety.org/uploads/pdfs/npc/npc.pdf. Accessed August 10, 2014.

Treatment Options

Non-Pharmacologic[1]	Pharmacologic[2]
• Acupuncture • Cognitive behavior therapy • Physical therapy • Spinal manipulation • Surgery • Transcutaneous electrical nerve stimulation • Yoga	• Acetaminophen • Adjuvant therapy • NSAIDs • Opioids • Skeletal muscle relaxants

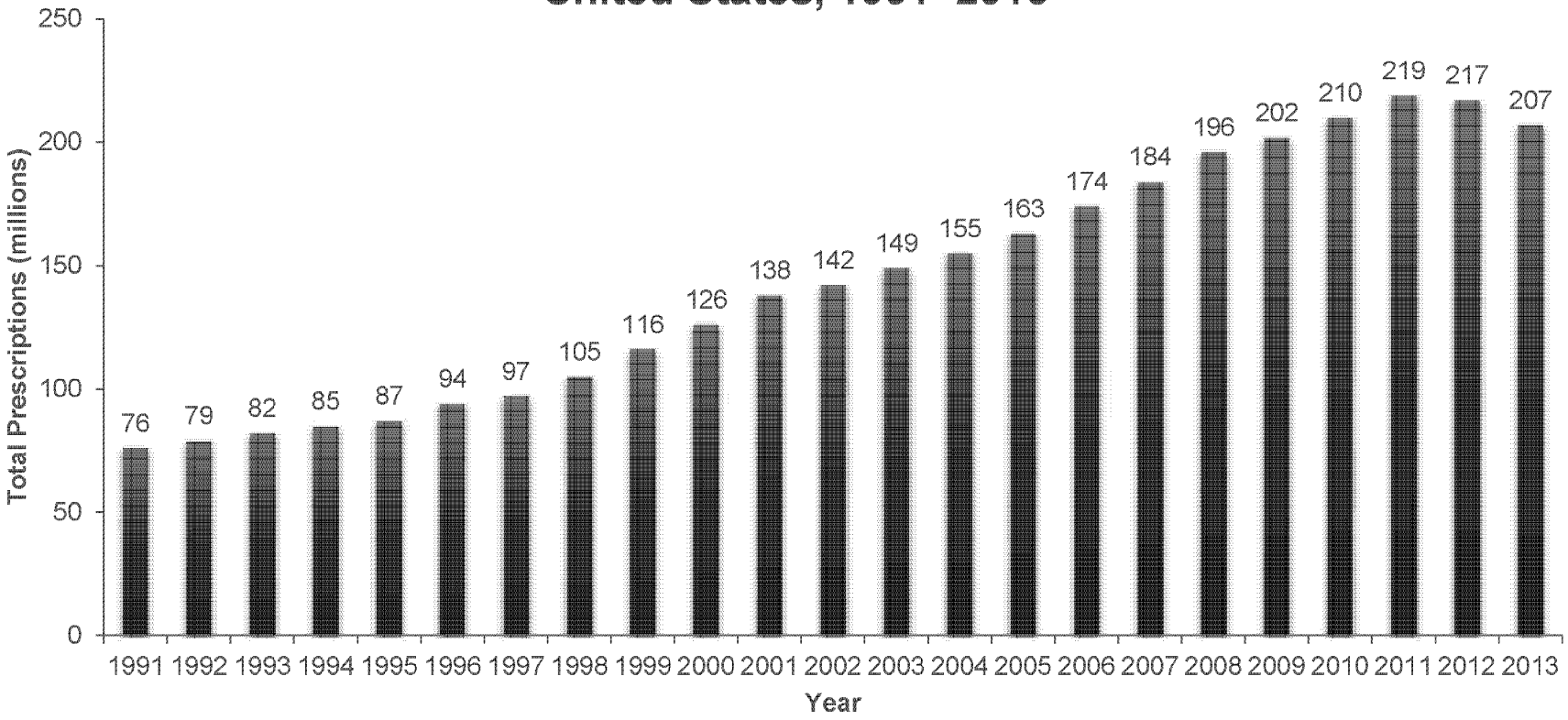
1. Chou R, Huffman LH. *Ann Intern Med*. 2007;147(7):492-504. **2.** Chou R, Huffman LH. *Ann Intern Med*. 2007;147(7):505-514.

ARS Question

- How often do you consider the use of non-pharmacologic therapy in patients who complain of pain?
  1. <25%
  2. 25% - <50%
  3. 50% - 75%
  4. >75%

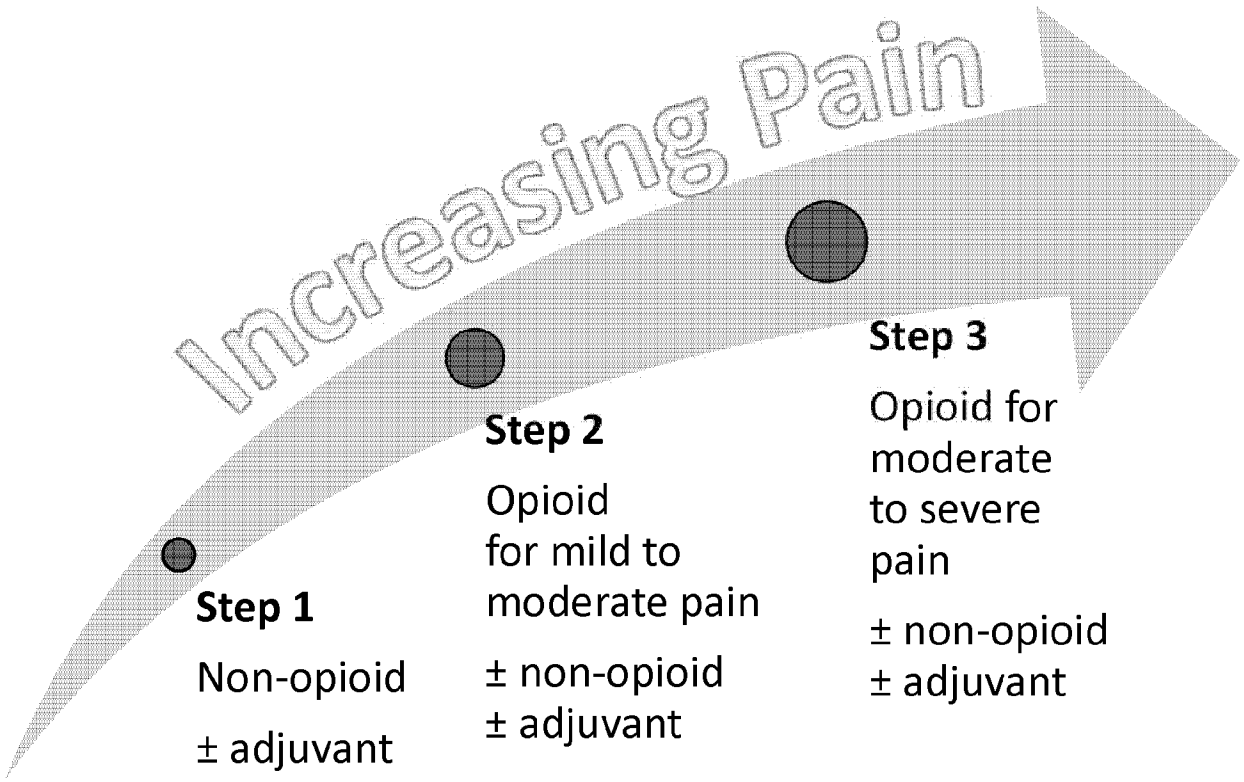
Opioids An Important Analgesic Option

Opioid Prescriptions Dispensed by Retail Pharmacies—United States, 1991–2013



Department of Health and Human Services/National Institutes of Health. Prescription Opioid and Heroin Abuse. Testimony by Nora Volkow, MD, Director, National Institute on Drug Abuse. http://democrats.energycommerce.house.gov/sites/default/files/documents/Testimony-Nora-Volkow-OI-Prescription-Drug-and-Heroin-Abuse-2014-4-29.pdf. Accessed August 2, 2014.

WHO Recommendations

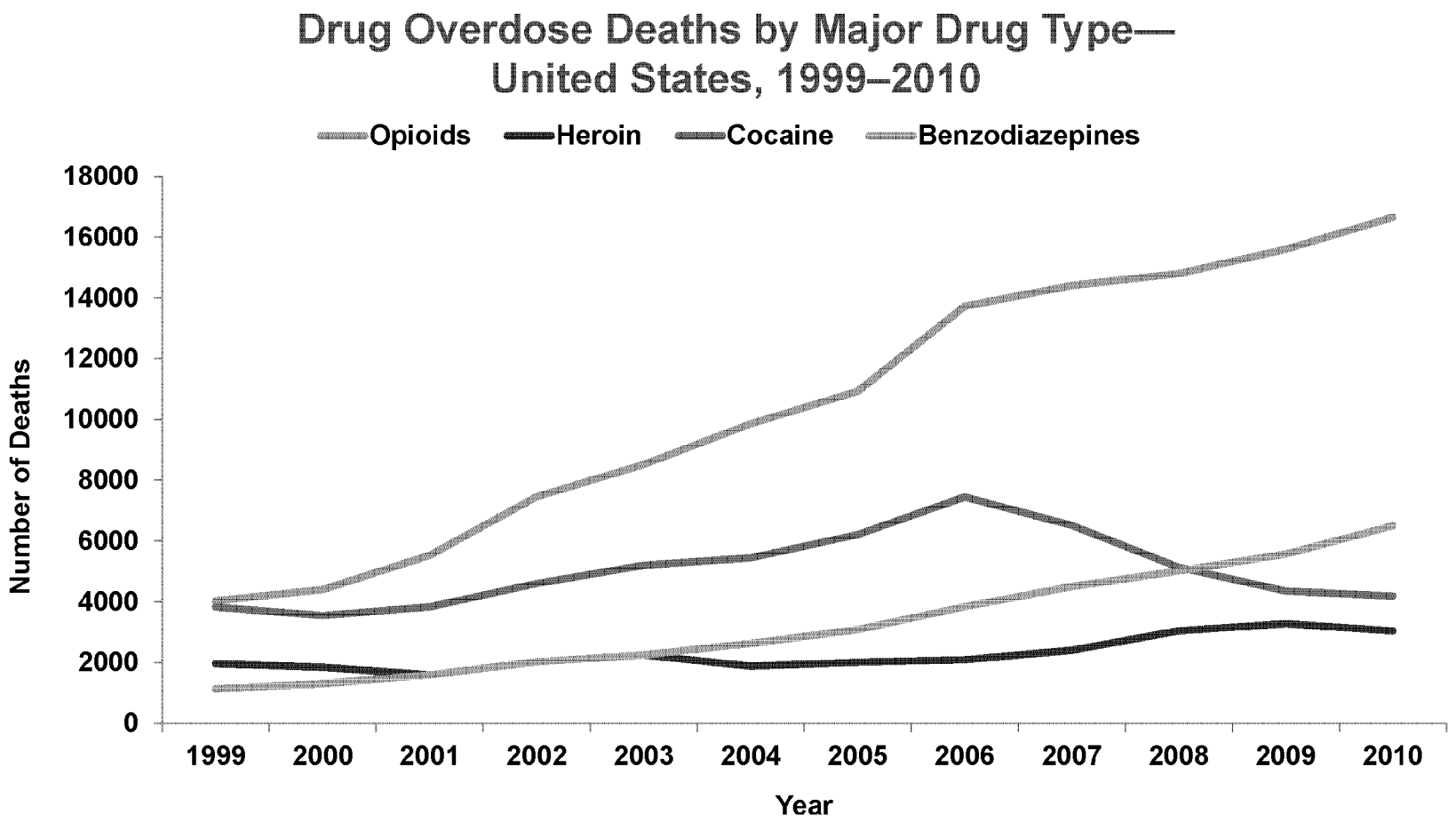


World Health Organization Cancer Pain Ladder for Adults. http://www.who.int/cancer/palliative/painladder/en/. Accessed August 24, 2014.

ARS Question

- Which of the following causes the most overdose deaths in the US?
  1. Heroin
  2. Cocaine
  3. Opioids
  4. Benzodiazepines

Unintended Consequences of Abuse

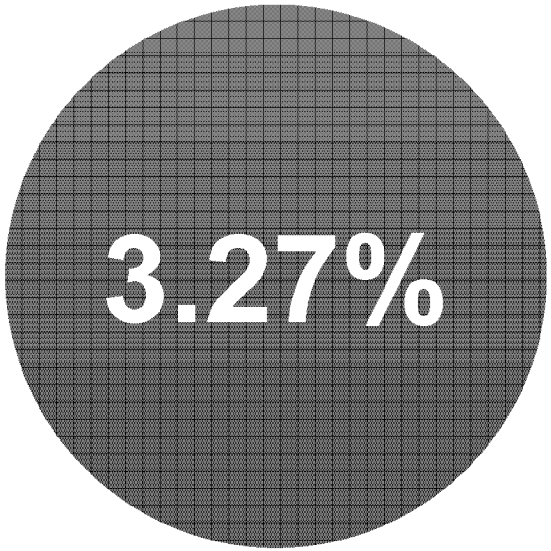


Centers for Disease Control. Primary Care and Public Health Initiative. Prescription Drug Abuse and Overdose: Public Health Perspective. October 24, 2012. http://www.cdc.gov/primarycare/materials/opoidabuse/. Accessed August 4, 2014.

ARS Question

- What percent of non-cancer patients on opioids for chronic pain develop abuse/addiction?
  1. <5%
  2. 10%
  3. 25%
  4. 50%
  5. >50?

What Is the Scope of Intended Abuse/Addiction?



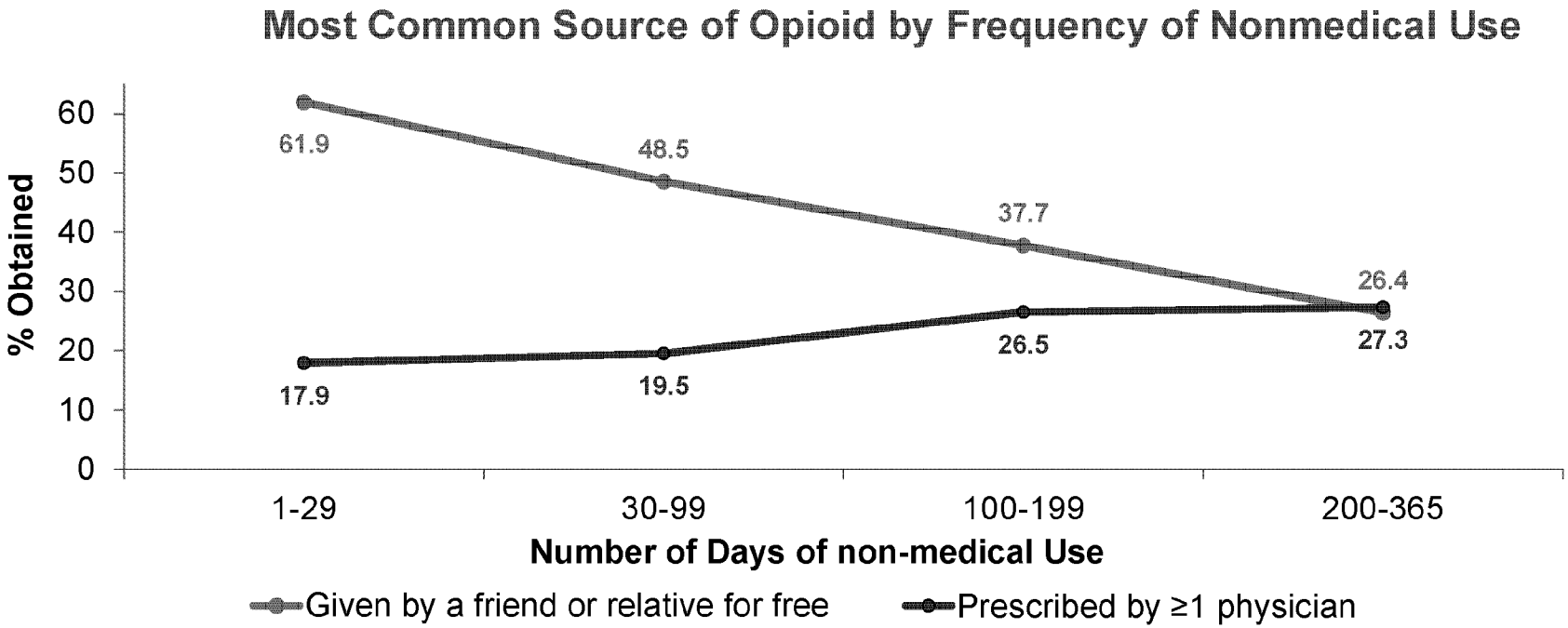
Percent of patients being treated with chronic opioid therapy with high likelihood of abuse/addiction

- Data derived from an evidence-based review of chronic pain patients with nonmalignant pain receiving chronic opioid analgesic therapy
- 67 studies that evaluated
  - Abuse/addiction rate (24 studies, n=2507)
  - Aberrant drug-related behaviors (ADRBs) (17 studies, n=2466)
  - Urine test results (5 studies, n=1965)
- **25x lower** rate of abuse/addiction in patients without a prior history (0.19% vs 5.0%)

Fishbain DA, et al. *Pain Med.* 2008;9(4):444-459.

Source of Opioid Diversion with Increasing Non-medical Use[1]

- Although the most common initial source of opioids for nonmedical use is through friends and family[1], the primary source changes with increased nonmedical use[2]



1. Substance Abuse and Mental Health Services Administration. http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.pdf. Updated October 2, 2013. Accessed March 31, 2014. **2.** Jones CM, et al. *JAMA Intern Med.* 2014;174(5):802-803.

Addressing Opioid Abuse: A Multi-Faceted Approach

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Professor of Neurology
Albany Medical College

Director, Comprehensive Pain Center
Albany Medical Center
Albany, NY

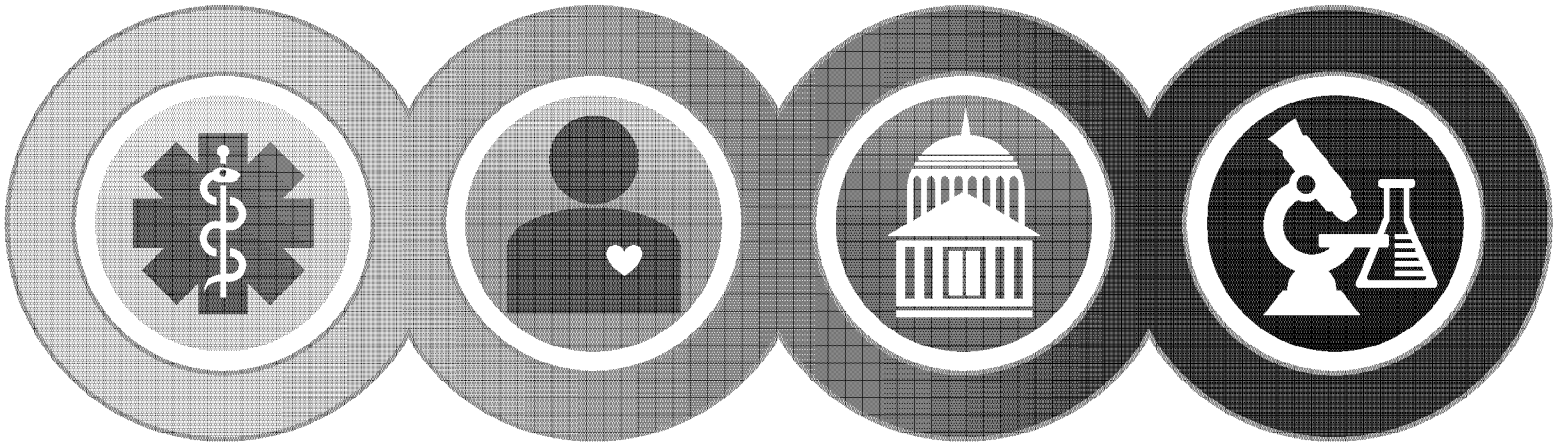
Approaches to Mitigate Opioid Abuse

- Education[1]
  - Clinician education on: appropriate prescribing, screening, monitoring, and patient management
  - Patient education on adherence, storage, and disposal
- Guidance and tools[1-5]
  - Prescription Drug Monitoring Programs (PDMPs)
  - Scheduling changes
  - Risk Evaluation and Mitigation Strategies (REMS)
  - Changes to opioid labeling
  - Abuse deterrent draft guidance from the FDA
- Developing abuse-deterrent formulations[1,5]

1. U.S. Food and Drug Administration. http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337852.htm#prescriber_education. Accessed July 28, 2014. **2.** U.S. Department of Justice . http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm. Accessed July 18, 2014. **3.** U.S. Food and Drug Administration. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367726.htm. Accessed July 19, 2014. **4.** Federal Register: The Daily Journal of the United States Government. Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II. http://www.gpo.gov/fdsys/pkg/FR-2014-08-22/pdf/2014-19922.pdf. Accessed August 25, 2014. **5.** U.S. Food and Drug Administration. Guidance for Industry: Abuse Deterrent Opioids – Evaluation and Labeling (Draft). January 2013. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf. Accessed July 20, 2014.

Stakeholders Addressing Opioid Abuse

A collaborative approach is necessary



HCPs | Patients | Government State + Federal | Industry

A multifaceted approach to mitigating risk is required to ensure safe and effective pain management

HCP Approaches to Mitigate Opioid Abuse

How often are these done in "low-risk" patients?

Universal Precautions

- Establishing diagnosis
- Treatment agreement
- Pain assessments
- Review of diagnosis
- Documentation

Screening

Various Instruments including:

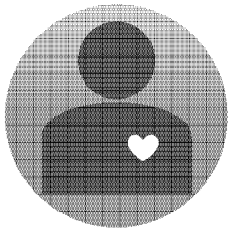
- Opioid Risk Tool (ORT)
- Current Opioid Misuse Measure (COMM)
- Revised Screener and Opioid Assessment for Patients with Pain (SOAPP-R)
- Pain Assessment & Documentation Tool (PADT)

Adherence Monitoring

- Prescription drug monitoring programs (PDMPs)
- Random drug screens
- Pill counts

HCPs are at the forefront of pain management and employ multiple methods to assess opioid risk in individual patients

Sehgal N, et al. *Pain Physician*. 2012;15(3 suppl):ES67-ES92.



Patient Responsibilities

Safe Use[1]

- Take medications as prescribed
- Understand risks
- Awareness of inappropriate use

Safe Storage[1,2]

- Keep opioids hidden or locked to avoid access by family or friends
- Never share opioids with others

Safe Disposal[1]

- Opioids may be disposed of through community-sponsored take-back programs
- If not available, environmentally friendly disposal should be undertaken per Office of Drug Control National Policy recommendations

1. Arnstein P, St. Marie B. Managing chronic pain with opioids: a call for change. December 2010. http://www.nphealthcarefoundation.org/programs. Accessed July 20, 2014. **2.** Broglio K, Cole BE. *Nurse Practitioner*. 2014:39(6):30-37.

What is a PDMP?

Prescription Drug Monitoring Program

- Definition
  - Statewide electronic database
  - Collects data on substances dispensed in state
  - Housed by designated state agency (eg, regulatory, administrative, law enforcement)
  - Accessible to authorized personnel
- Benefits
  - Supports legitimate access to controlled substances
  - Identifies and deters drug abuse and diversion
  - Facilitates identification and treatment of those addicted to prescription drugs
  - Provides use and abuse data to inform public health efforts
  - Educates individuals on use, abuse, and diversion

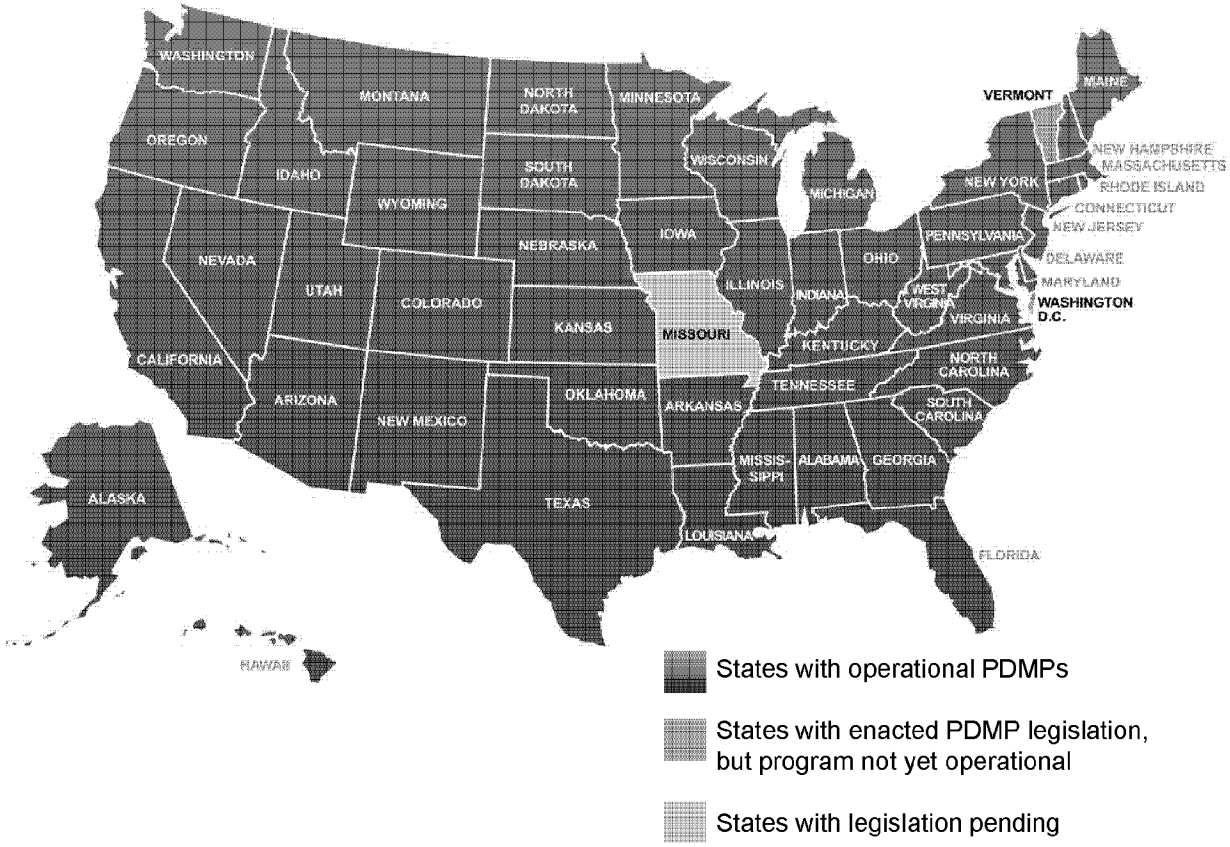
U.S. Department of Justice. http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm. Accessed July 18, 2014.

ARS Question

- How many states have an operational PDMP in place?
  1. 46
  2. 47
  3. 48
  4. 49
  5. 50

PDMPs State by State[1]

- PDMPs vary by state based on[2]:
  - Prescriptions tracked
  - Which prescribers must report
  - Lag time in reporting
  - Access to data
  - PDMPs may modify prescribing behavior, reduce "doctor shopping," and speed investigations



The full benefit of PDMPs will not be reached until all states implement data sharing and interoperability between each other[2]

1. NAMSDL. http://www.namsdl.org/library/16666FCC-65BE-F4BB-A2BBAD44E1BC7031. Accessed July 18, 2014.
2. Finklea K, et al. Congressional Research Service. March 24, 2014. fas.org/sgp/crs/misc/R42593.pdf. Accessed August 7, 2014.

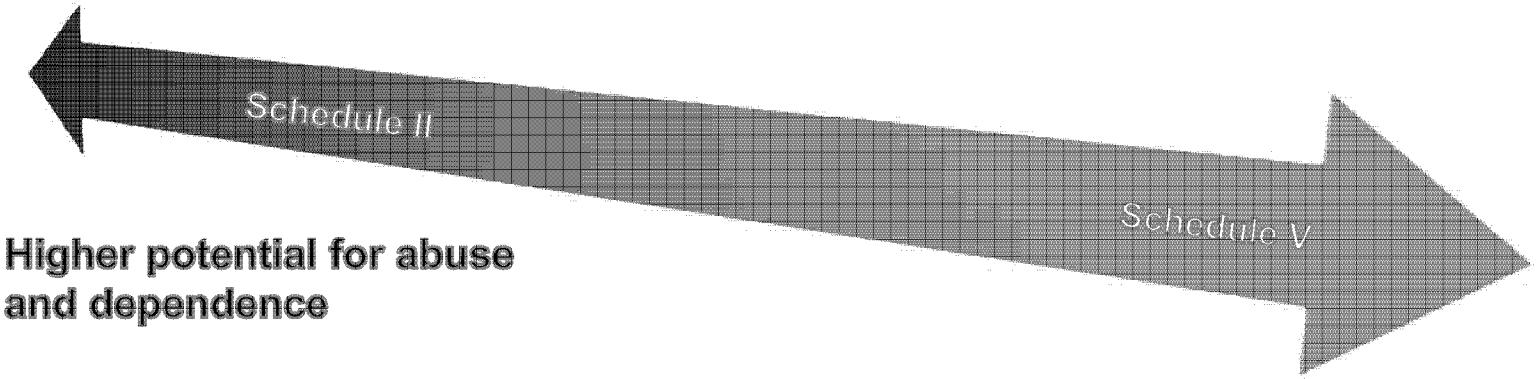
Medicaid "Lock-In" Program

1 Patient, 1 PCP, 1 Pharmacy

- **The Law**
  - Federal law allows Medicaid to restrict patients who overutilize Medicaid services to designated providers
- **The Application**
  - High-risk opioid users can be restricted ("locked in") to receive treatment and prescriptions from a designated PCP and/or pharmacy
- **The Purpose**
  - Single provider can coordinate care
  - Reduces doctor/pharmacy shopping
  - Limits drug diversion
  - Reduces healthcare utilization and pharmacy costs
- **Future**
  - Lock-in programs might be adopted by other governmental payers and possibly private insurers as well

Roberts AW, Skinner AC. *J Manag Care Pharm*. 2014;20(5):439c-446c.

DEA Changes to Opioid Scheduling



Higher potential for abuse and dependence

Lower potential for abuse and dependence

Drug Enforcement Administration. http://www.justice.gov/dea/druginfo/ds.shtml. Accessed July 19, 2014.

Opioid Risk Evaluation and Mitigation Strategies (REMS)

1. Medication Guide or patient Package Insert[1,2]
2. Communication Plan[1] *
3. One or more elements to assure safe use[1,2]
4. Implementation System[1,2]
5. Timetable for reporting REMS assessments[1,2]

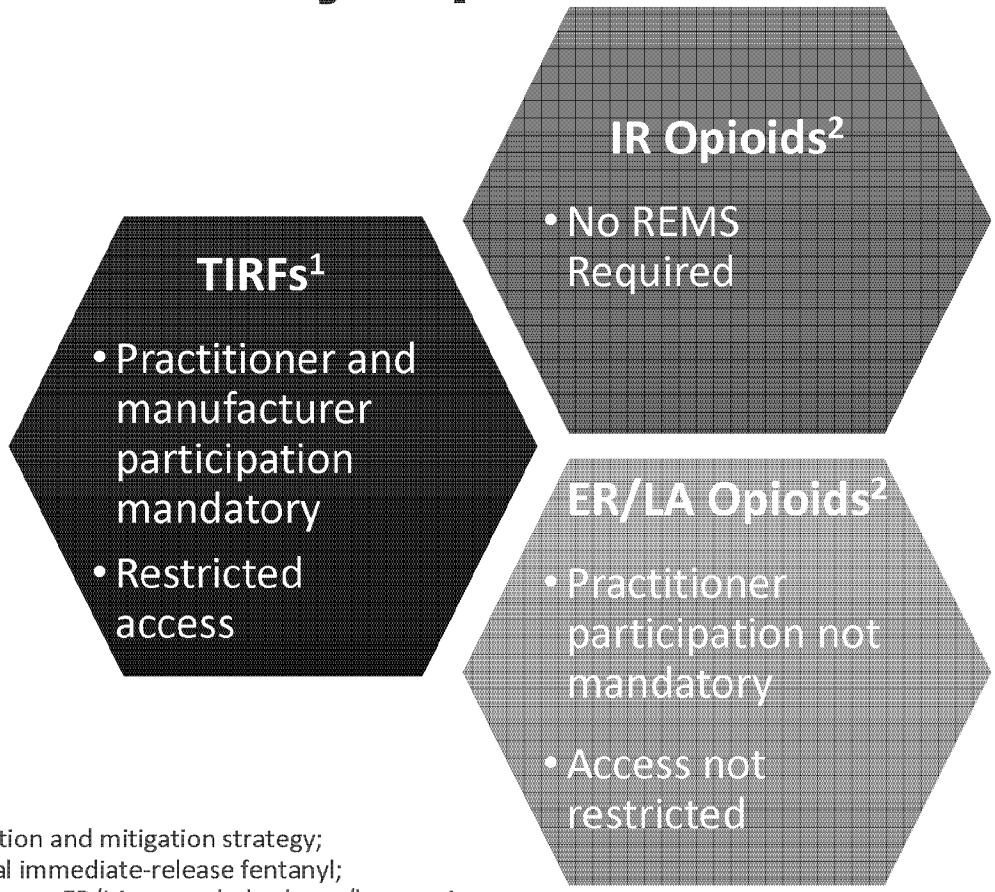
*Required for REMS specific to transmucosal immediate-release fentanyl (TIRF) drugs but not extended-release/long-acting (ER/LA) opioids REMS.[1-2]

1. U.S. Food and Drug Administration. http://www.fda.gov/downloads/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm311290.pdf. Accessed July 19, 2014. **2.** U.S. Food and Drug Administration. http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm284717.htm. Accessed July 19, 2014.

ARS Questions

- True or false: REMS are only associated with opioids.
  1. True
  2. False

REMS Programs Differ by Opioid Class



REMS, risk evaluation and mitigation strategy;
TIRF, transmucosal immediate-release fentanyl;
IR, immediate-release; ER/LA, extended-release/long-acting

1. U.S. Food and Drug Administration. http://www.fda.gov/downloads/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm311290.pdf. Accessed July 19, 2014. **2**. U.S. Food and Drug Administration. http://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm309742.htm. Accessed July 19, 2014.

Recent FDA Labeling Changes for ER/LA Opioids

INDICATION CHANGE #1
ER/LA opioids are indicated for management of pain severe enough to require daily, around the clock, long-term opioid treatment and for which alternative treatments are inadequate

POST-MARKETING STUDIES
FDA requires new studies to further assess the known serious risks of misuse, abuse, increased sensitivity to pain (hyperalgesia), addiction, overdose, and death

INDICATION CHANGE #2
Should be reserved for use in patients for whom alternative treatment options (eg, non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain

NEW BOXED WARNING
Chronic maternal use of these products during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS)

U.S. Food and Drug Administration. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367726.htm. Accessed July 19, 2014.

A Multi-Faceted Approach to Addressing Opioid Abuse

- Key stakeholders in addressing opioid abuse include HCPs, patients, and government
- HCP strategies for mitigating opioid abuse include universal precautions, screening for drug abuse and abuse risk, urine testing, and adherence monitoring
- Patients should be educated on the methods and importance of safe use, safe storage, and safe disposal of opioids
- The federal and state governments have developed and are developing programs aimed at making opioid diversion and abuse more difficult and less likely, including:
  - PDMPs
  - REMS
  - Labeling changes
- Industry may also have a role by developing abuse-deterrent opioids

Developing Abuse-Deterrent Opioids

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Associate Medical Director
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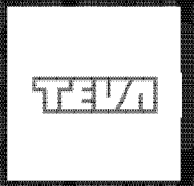
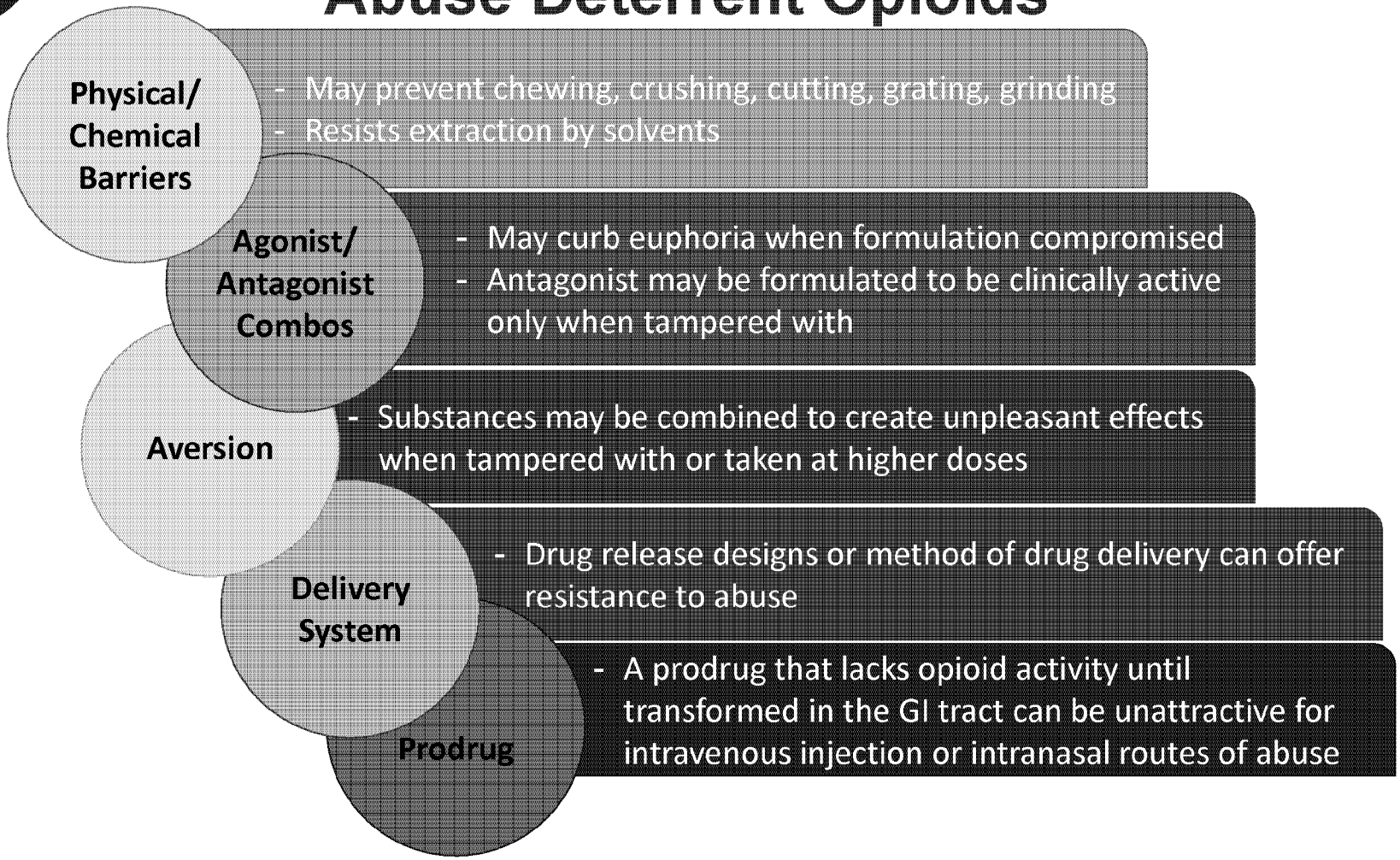
Silver Hill Hospital
New Canaan, CT



ARS Question

- What is the most common method of opioid abuse?
  1. Injecting
  2. Snorting
  3. Crushing
  4. Oral overconsumption

Various Approaches to Abuse Deterrent Opioids

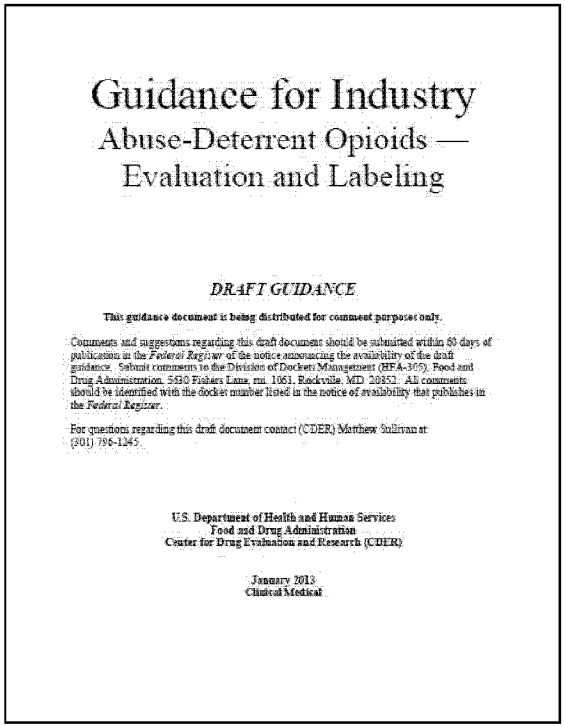


U.S. Food and Drug Administration. Guidance for Industry: Abuse Deterrent Opioids – Evaluation and Labeling (Draft). January 2013. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf. Accessed July 20, 2014.

FDA Draft Guidance on Abuse-Deterrent Opioids

Provides guidance on studies that should be conducted:

- ***To demonstrate that a formulation has abuse-deterrent properties***
- ***How those studies will be evaluated***
- ***What labeling claims may be proposed based on the results of those studies***



Guidance for Industry

Abuse-Deterrent Opioids — Evaluation and Labeling

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Matthew Sullivan at (301) 796-1245.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

January 2013
Clinical Medical

U.S. Food and Drug Administration. Guidance for Industry: Abuse Deterrent Opioids – Evaluation and Labeling (Draft). January 2013. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf. Accessed July 20, 2014.

ARS Question

- Which of the following is addressed in the 2013 FDA Draft Guidance for Abuse-Deterrent Opioids?
  1. Categories of studies to evaluate abuse-deterrent properties
  2. Designs and goals of such studies
  3. Examples of labeling claims that could be proposed based on the results of these studies
  4. All of the above

FDA Draft Guidance for Abuse-Deterrent Opioids

- FDA guidance document outlines:
  - Categories of studies to evaluate abuse-deterrent properties
  - Designs and goals of such studies
  - Examples of labeling claims that could be proposed based on the results of these studies

Categories of Studies

1 Laboratory Manipulation and Extraction Studies
- Evaluate how easily the formulation can be manipulated

2 Pharmacokinetic Studies
- Evaluate in vivo PK profiles of manipulated and intact drug vs comparator

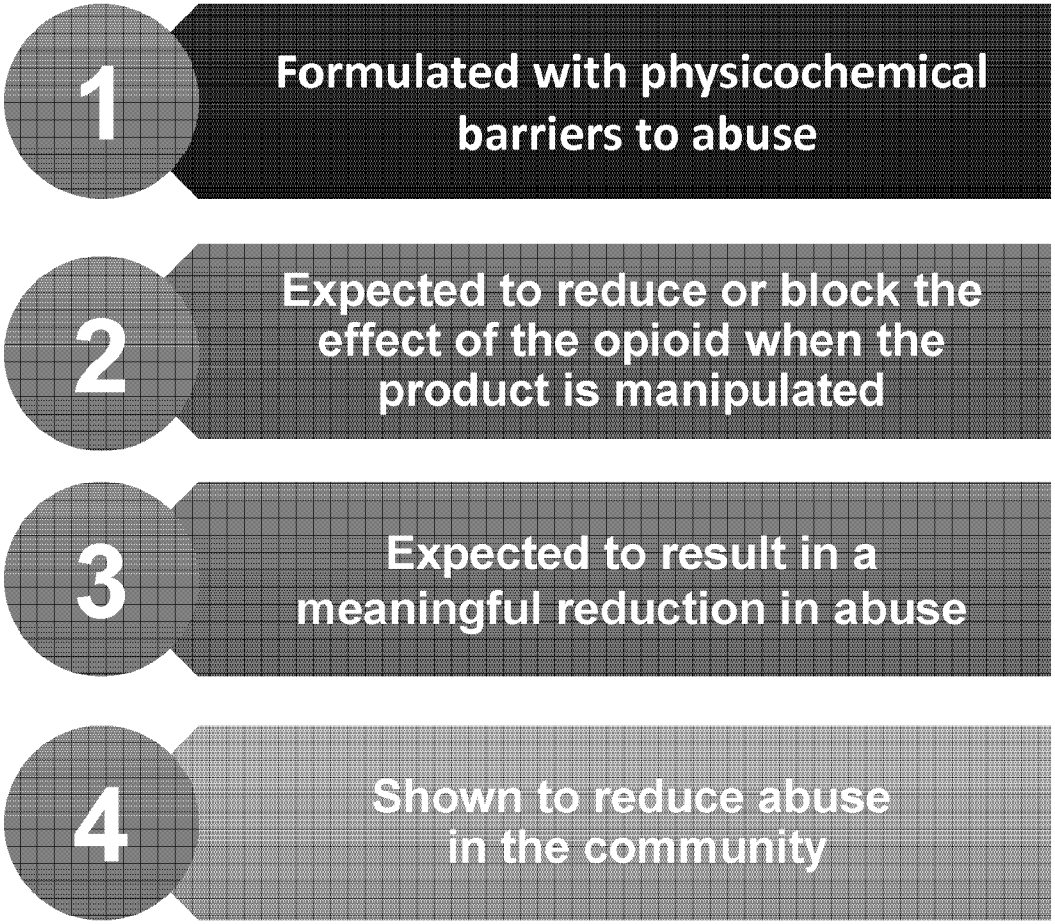
3 Clinical Abuse Potential (CAP) Studies*
- Assess impact on appeal to abusers (ie, drug liking)

4 Postmarketing Studies
- Determine if formulation results in lower levels of abuse vs non-deterrent formulations

*Also called human abuse liability (HAL) studies.

U.S. Food and Drug Administration. Guidance for Industry: Abuse Deterrent Opioids – Evaluation and Labeling (Draft). January 2013. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf. Accessed July 20, 2014.

Four Tiers of Label Claims



U.S. Food and Drug Administration. Guidance for Industry: Abuse Deterrent Opioids – Evaluation and Labeling (Draft). January 2013. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf. Accessed July 20, 2014.

ARS Question

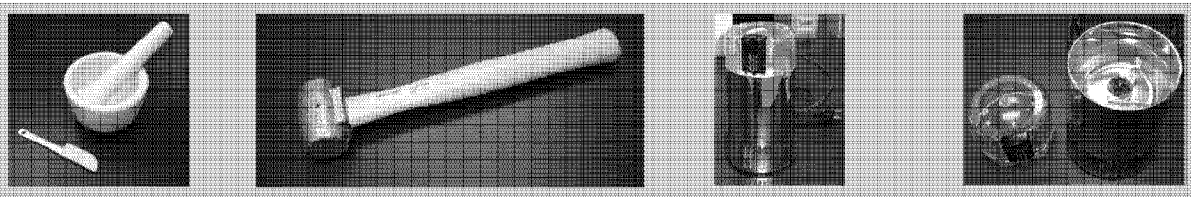
- What type of study may be required to show a reduction of abuse in the community?
  1. Laboratory manipulation and extraction
  2. Pharmacokinetic
  3. Human abuse liability (HAL)
  4. Postmarketing
  5. All of the above

FDA Draft Guidance for Laboratory Manipulation and Extraction Studies

Study Design

Mechanical Manipulation Studies

- Focus on **particle size**, which may influence opioid extractability
- Ordinary tools/utensils should be employed in testing; eg, spoons, cutters, and coffee grinders



- Effect of **heat** and **cold** on mechanical manipulation

Solubility Studies

- Determine ease of **solubility** with various solvents (eg, water, vinegar, ethanol, isopropanol, acetone, mineral spirits)

Route-Specific Evaluation

- ***Snorting*:** particle size distribution
- ***Smoking*:** vaporization temperature
- ***Injection*:** opioid concentration in small injection volume and viscosity of injection fluid

U.S. Food and Drug Administration. Guidance for Industry: Abuse Deterrent Opioids – Evaluation and Labeling (Draft). January 2013. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf. Accessed July 20, 2014.

FDA Draft Guidance for Pharmacokinetic (PK) Studies

Study Design

Pharmacokinetic Parameters

- Maximum plasma concentration (C_{max})
- Time to reach C_{max} (T_{max})
- Area under the curve (AUC)
- Relevant partial AUC (eg, $AUC_{0\text{-}30mins}$ or $AUC_{0\text{-}2hrs}$)
- Terminal elimination half-life

Areas of Special Interest Comparing Intact and Manipulated Formulations

- Rate of rise of drug concentration (thought to contribute to abuse potential)
- Determination if food affects systemic exposure to formulation
- Recording of incidence and nature of adverse events

U.S. Food and Drug Administration. Guidance for Industry: Abuse Deterrent Opioids – Evaluation and Labeling (Draft). January 2013. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf. Accessed July 20, 2014.

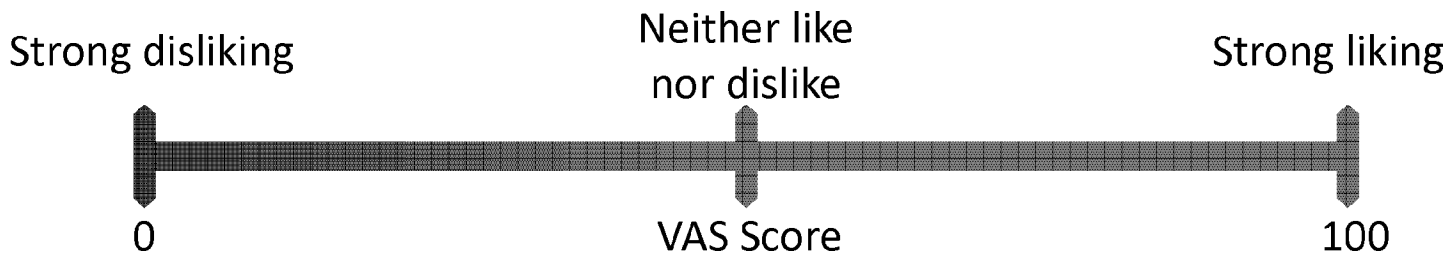
FDA Draft Guidance for CAP* Studies

Study Assessments

Measurements of Interest

- Drug liking (eg, How much did you like the drug?")
- Assessment of high (eg, "How high are you?")
- Good effects (eg, euphoria)
- Bad effects (eg, specific AEs)
- Likelihood to use drug again (eg, "How likely are you to use this drug again?")

Bipolar Scale



*Clinical abuse potential; also referred to as human abuse liability (HAL) studies.

U.S. Food and Drug Administration. Guidance for Industry: Abuse Deterrent Opioids – Evaluation and Labeling (Draft). January 2013. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf. Accessed July 20, 2014.

FDA Draft Guidance for Postmarketing Studies

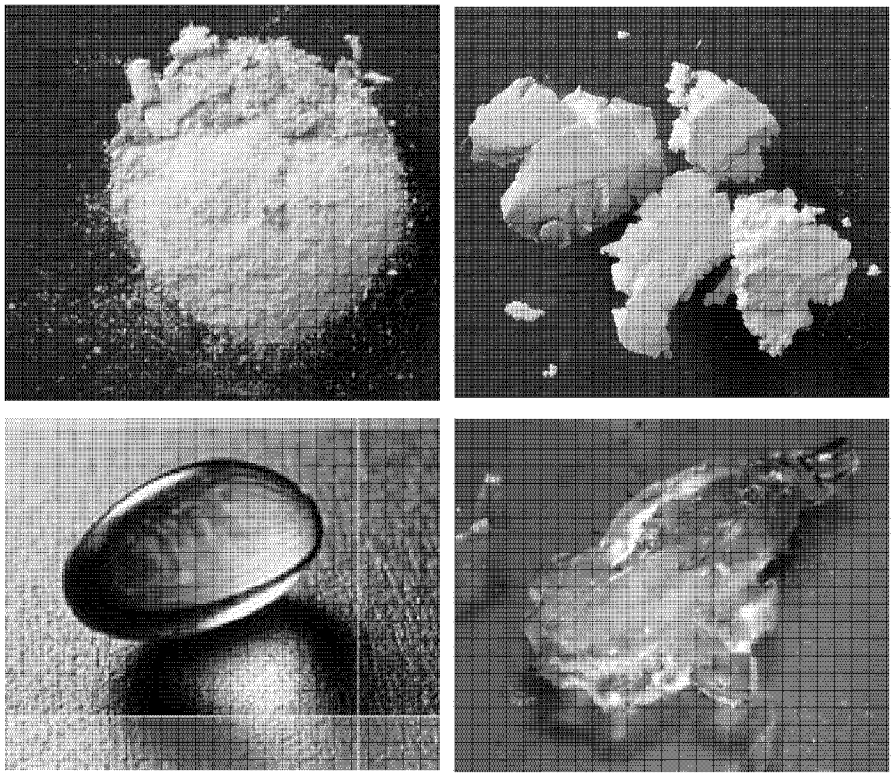
Study Characteristics	• Use outcomes that provide meaningful measures of abuse deterrence • Produce estimates of abuse deterrence that are nationally representative, or are based on data from a large geographic region • Assess overall and route-specific abuse and abuse deterrence • Are sufficiently powered to assess meaningful changes in drug abuse
	Study Population • Should be carefully selected (ie, relevant to real-world abuse) • At least one study should include high-risk subjects (eg, drug abusers)
	Use of a Comparator • Comparator is critical to rule out other factors (eg, educational interventions, law enforcement changes) • Other opioids as comparator is encouraged

U.S. Food and Drug Administration. Guidance for Industry: Abuse Deterrent Opioids – Evaluation and Labeling (Draft). January 2013. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf. Accessed July 20, 2014.

Abuse-Deterrent Formulations: Crush-Resistant Pills and Capsules

How abuse-deterrent is it?

- Recent formulations seek to make crushing pills unusable for abuse
- In this form, drug may be challenging to break, snort, chew, inject
- Crush-resistant pill currently available
- Gelatin capsule rejected by FDA in 2011
- Labeling differentiates between formulations that *prevent* abuse and those that make it *more difficult*



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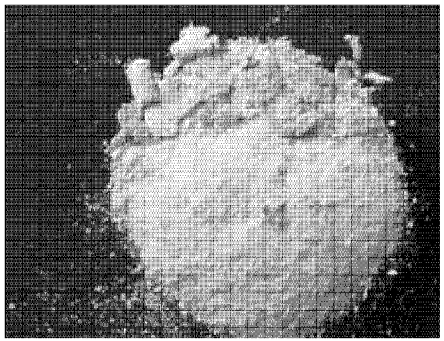

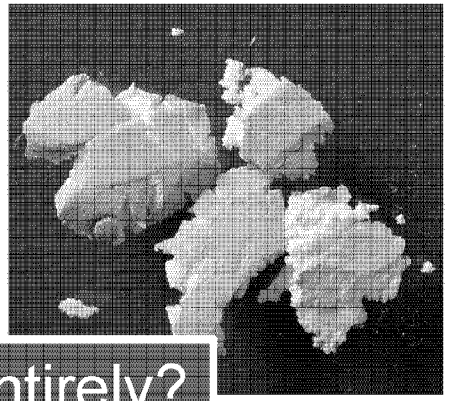

How abu… deterre… is it?

But does this approach prevent abuse entirely?

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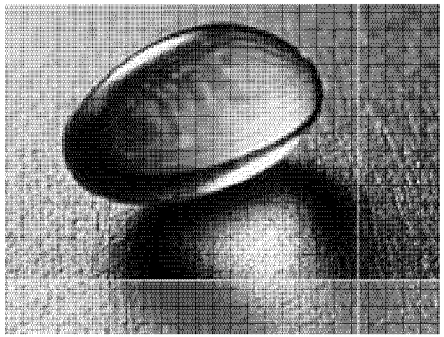
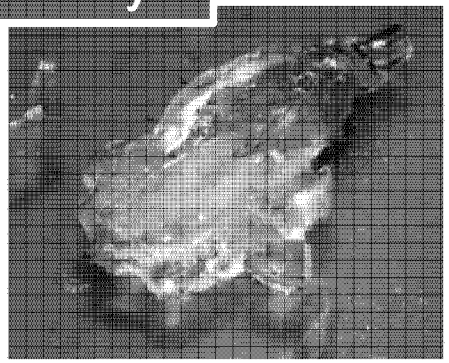
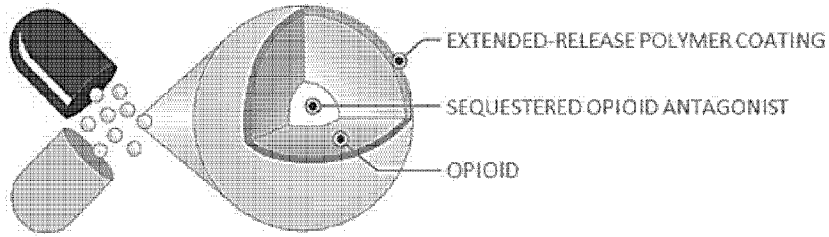




Abuse-Deterrent Formulations: Agonist-Antagonist

Mixing the bad with the good

- Capsule containing many pellets of opioid
- Sequestered core contains an opioid antagonist
- No notable antagonist effect if taken orally or if pellets are sprinkled on food
- If crushed or chewed, antagonist is released, causing withdrawal symptoms



Moorman-Li R, et al. *P & T*. 2012;37(7):412-418.

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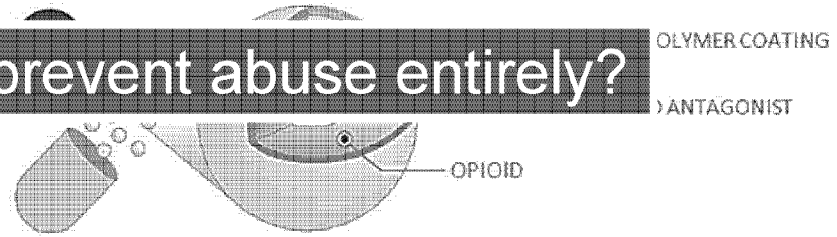

Moorman-Li R, et al. *P & T*. 2012;37(7):412-418.

ARS Question

- For what % of your patients would you consider an abuse-deterrent opioid formulation?
  1. 0%
  2. 25%
  3. 50%
  4. 75%
  5. 100%

The Continuing Evolution of Abuse-Deterrent Opioids

- Numerous approaches to deter abuse have been, and are being, developed to decrease the likelihood of opioid misuse, abuse, and diversion
- The FDA has provided industry with draft guidance for the development and testing of new abuse-deterrent formulations
- The draft guidance also includes levels of claims manufacturers may propose in labeling to describe the potential abuse-deterrent properties of a product based on study results

Addressing the Opioid Epidemic: Conclusions

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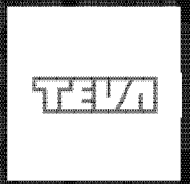

Conclusions

- Pain is a major reason patients seek medical care, and opioids remain an important treatment option for adequate analgesia
- Addressing issues surrounding opioid misuse, abuse, and diversion requires a multi-faceted approach that encompasses HCPs, patients, government, and industry
- While no abuse-deterrent opioid formulations prevent all types of abuse, they may be designed to provide an additional barrier to opioid abuse
  - Education, guidance and tools continue to be the most important impediments to abuse
  - Continued development and availability of abuse-deterrent opioids may further diminish the likelihood of abuse